REMARKS/ARGUMENTS

Claims 15-21, 24, 31-43 and 53-60 were examined and rejected. Applicant believes the claims as originally filed and previously presented are patentable, but have amended to expedite prosecution and clarify the invention. Applicants cancel no claims and amend claims 15 and 31. Applicants submit that no new matter is added therein as the amendment to claim 15 is supported at least by paragraphs 56-58 and FIG. 1 of the application; and amendment to claim 31 is supported at least by claim 33. Hence, Applicants respectfully request reconsideration of pending claims 15-21, 24, 31-43 and 53-60.

I. Claims Rejected Under 35 U.S.C. § 102

The Patent Office rejects claims 15, 31, 32, 35-36 and 54 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,810,007 to Holupka et al. (Holupka). It is axiomatic that to be anticipated every limitation of a claim must be disclosed in a single reference.

Applicants respectfully disagree with the rejection above of claim 31 for at least the reason that the cited references do not disclose imaging a plurality of markers and an in vivo landmark using a first imaging modality, imaging the plurality of markers in a second modality, wherein the in vivo landmark is not imageable in the second modality, and monitoring in vivo at least one physiological parameter of the body, as required by amended claim 31. Specifically, Holupka teaches ultrasound probe 12 having transducer array 18 and fiducials 20 and 22 that are imaged in both the ultrasound image (FIG. 3) and in the simulator film image (FIG. 4) (see column 4 lines 2-17).

The Patent Office argues on page 3 of the current Office action that the "physiological parameter" can be described by monitoring the location of prostate relative to landmark, as taught in Holupka. Applicant asserts that this is an unreasonable interpretation of the terms "physiological parameter," and notes that neither common usage nor the art of record supports a definition of physiological parameter as a location of an organ. Claim 31 requires monitoring a physiological parameter; and correlating a position of an in vivo landmark relative to at least one of a plurality of markers. Thus, defining the claimed "physiological parameter" as monitoring the position of the prostate relative to the marker as asserted by the Patent Office is unreasonable in view of the current record, and Applicants respectfully request the Patent Office provide a

reference in support of this position in accordance with MPEP Section 2144.03. Applicants assert that the Patent Office cannot "have it both ways" and must use a claim interpretation that is objectively reasonable, and at the least not internally inconsistent. Consequently, the Patent Office has not identified and Applicants are unable to find any disclosure or teaching of the above noted limitations of amended claim 31.

Applicants respectfully disagree with the rejection above of independent claim 15 for at least the reason that the cited reference does not disclose an internal coordinate system based on a plurality of markers at least one of which is other than and not physically attached to the sensor, as required by amended claim 15.

As noted by the Patent Office, ultrasound probe 12 of Holupka includes fiducials 20 and 21 on the ulatrasound probe 12. Consequently, the Patent Office has not identified and Applicants are unable to find any disclosure or teaching of the above noted limitations of amended claim 15.

II. Claims Rejected Under 35 U.S.C. § 103

Claims 15-21, 24, 43, 53, and 59-60 are rejected under 35 U.S.C. § 103(a) as being unpatentable in view of U.S. Patent Publication No. 2002/0077543 to Grzeszczuk, et al. (Grzeszczuk) in view of U.S. Patent No. 6,402,689 to Scarantino et al. ("Scarantino"). Claims 33, 34 and 37-42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Holupka. Claims 55-58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Holupka in view of Scarantino. For a claim to be obvious, each limitation of that claim must be taught or suggested by at least one properly combined reference.

Applicants disagree with the rejection above for claim 15 for at least the reason the cited references do not teach or suggest identifying a position of the sensor device relative to an internal coordinate system using an imaging technique, wherein the internal coordinate system is based on a plurality of markers at least one of which is other than and not physically attached to the sensor located in the body and having an imageable marker property, and wherein identifying comprises identifying the position relative to at least one of the plurality of markers, as required by amended claim 15.

Grzeszczuk teaches a method and system for tracking a medical instrument as it moves in an operating space of a patient (see abstract). Grzeszczuk teaches that the medical instrument

may be a catheter having flexible or rigid construction (see paragraph 35). Grzeszczuk teaches that each of the C-arm/image intensifier and surgical instrument is equipped with optical emitters, such as light-emitting diodes (LED) markers which are in communication with optical tracking device or position sensor 20 to provide a local coordinate system (see paragraph 35). Thus, during registration, the C-arm to CT data set registration can be used together with the position and orientation of the camera in the reference frame of tracking device 20 (see paragraph 39). Thus, it is possible to back-project the surgical tool into the CT data set previously acquired during a pre-operative CT data scan (see paragraphs 41 and 37). Consequently, misregistration due to patient movement or system error can be corrected by comparing a pre-operative CT data set with an actual fluoroscopic image which may include comparing fiducials or skeletal landmarks of the pre-operative data and the current fluoroscopic image (see paragraphs 40, 51 and 56). This helps guiding the surgical tool (see paragraph 56). However, there is no teaching, conception, enablement or motivation in Grzeszczuk of markers and a sensor device in the patient, and identifying a position of the sensor device relative to an internal coordinate system using an imaging technique, wherein an internal coordinate system is based on the markers other than the sensor, as required by claim 15.

Scarantino describes an in situ located sensor to allow monitoring of in vivo physiological parameters (see abstract). However, Scarantino does not provide the above noted limitations of claim 15. For example, Scarantino does not provide identification of a position of a sensor device relative to an internal coordinate system using an imaging technique, where the internal coordinate system is based on a plurality of markers other than the sensor, as required by claim 15.

In addition, by claiming an internal coordinate system based on a plurality of markers at least one of which is other than the sensor located in the body, some embodiments described in the specification, without limitation thereto, provide one or more benefits which may include more accurately positioning a sensor within a location of a body that deforms or distorts by implanting markers and the sensor into the anatomical area that distorts so that a more accurate position of the sensor may be determined (see new claim 59) to more accurately measure delivery of radiation to certain areas to ensure a target volume receives sufficient radiation and that injury to the surrounding and adjacent non-target volumes is minimized (see new claim 60),

such as described at paragraph 58, 81 and 88 of the application. However, none of the cited references conceive of or provide the above-noted benefits.

In addition to being dependent upon allowable base claim 15, applicants disagree with the rejection above of dependent claim 16 for at least the reason that the references do not teach injecting a sensor using a needle, where the position of the sensor relative to an internal coordinate system is identified based on a plurality of markers other than the sensor, as required by claim 16. The combination of the references is improper to provide the above noted limitations of claim 16. Specifically, Grzeszczuk teaches a catheter device including LED's which must remain external to the body (see at least FIG. 1 and LED's 18A and device 18 and paragraph 35). Consequently, a practitioner would not attempt to inject such a device into tissue through a hypodermic needle as such a practice would defeat the primary purpose and principle of operation of Grzeszczuk.

In addition to being dependent on allowable base claim 15, Applicants disagree with the rejection above of dependent claim 18 for at least the reason that the references do not teach a sensor device having a length less than approximately 26 millimeters, as required by claim 18. Applicants disagree for at least the reason that a practitioner would not combine the injectable or greatly reduced size device of Scarantino with Grzeszczuk as suggested by the Patent office. A practitioner would not attempt to create an injectable or greatly reduced size version of the Grzeszczuk catheter because doing so would defeat the primary purpose and principle of operation of Grzeszczuk of using a device including LED's which must remain external to the body. For example, Grzeszczuk only teaches medical devices being catheters or markers, neither of which would motivate a practitioner to conceive of a sensor for injection by a needle as required by claim 16, or a sensor having a length, as required by claim 18. Hence, for these additional reasons, Applicants respectfully request the Patent Office withdraw the rejection above of claims 16 and 18.

In addition to being dependent on allowable base claim 15, Applicants disagree with the rejection above of dependent claim 21 for at least the reason that the cited references do not disclose tracking the position of the sensor device over time as the body moves, as required by claim 21. Grzeszczuk discloses a principle of operation that an initial registration of the patient's anatomy is performed (see paragraph 38), but that the technique does not enable real-time DRF for the sake of target movement monitoring, and thus the periodic re-registration principle of

operation is required to correct misregistration by reacquiring new fluoroscopic images and running a fairly automatic procedure (see paragraph 56). It can be appreciated that this re-registration requirement teaches against tracking the position of the sensor over time as the body moves, since it requires a reacquisition of images and running a procedure to complete the re-registration (see paragraph 38).

In addition to being dependent upon allowable base claims, Applicants disagree with the rejection above of dependent claims 17, 43, 57 and 58 for at least the reason that a person skilled in the art would not attempt to implant a sensor through injection upon reading Grzeszczuk. An argument analogous to the one above for claim 16 applies here as well to show that such a practice would defeat the primary purpose and principle of operation of Grzeszczuk. Moreover, Applicants traverse the rejection of claims 17, 43, 57 and 58 and respectfully request the Patent Office provide a reference in support of its position in accordance with MPEP § 2144.03.

Each dependent claim not noted above is patentable for the reasons discussed above for its base claim, in addition to the further non-obvious limitations added by each dependent claim.

Hence, Applicants respectfully request the Patent Office withdraw the rejection for all the claims for at least all the reasons above.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes a telephone conference would be useful in moving the case forward, he is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted to the United States Patent and Trademark Office electronically via EFS Web on the date shown below.

Jessica Huester — 01/08/09
Date